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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,355	01/31/2005	Robert J. Hariri	9516-149-999	2178

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EXAMINER
BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/511,355	Applicant(s) HARIRI ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): the rejection of claim 2 under 35 U.S.C. § 112, second paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation Sheet for Advisory Action

Continuation of Box 11. The request for reconsideration has been fully considered, but it does NOT place the application in condition for allowance because it does not overcome the enablement and art rejections of record.

Enablement

Regarding the rejection of claim 11 under 35 U.S.C. § 112, first paragraph, applicant alleges that the specification provides adequate guidance for differentiating CD34+ hematopoietic stem cells to CD33+ cells by contacting them with a compound of Formula VII (Remarks, page 6, paragraph 2, through page 7, paragraph 2). Applicants point specifically to Example 11, which begins at page 76 of the as-filed specification, and recites in part:

> SelCIDs™ [selective cytokine inhibitory drugs; see page 25, lines 29-30] can significantly alter the development of [dendritic cells] from CD34+ progenitors ... SelCIDS™ treated CD34+ cells **are expected to acquire** the CD33 myeloid marker, and these cells will present a CD34+CD38-CD33+ phenotype at day 6 (beginning at page 76, line 31, **emphasis** added).

First, claim 11 is not limited to differentiating CD34+ cells to CD33+ cells; the claim allows that the cells may be CD33-. Second, the examples appear to be prophetic in nature, and no experimental data is presented in the specification. The examples recite prophetic language ("are expected to express," "is expected to inhibit"), and it is not clear that the skilled artisan would have had a reasonable expectation of success in performing these experiments and yielding the claimed cell populations at the time of the invention. There are no working examples in which Formula VII is specifically administered to cells and the results of said administration observed. If little is known in

the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004): "Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology" (citations omitted). See M.P.E.P. § 2164.03.

Obviousness

Regarding the rejections of the remaining pending claims under 35 U.S.C. § 103(a), applicants allege that the cited art does not suggest the substitutions and optimizations set forth by the examiner and that the cited art does not provide motivation to do so or an reasonable expectation of success in doing so (Remarks, page 7, last paragraph; page 9, second and fifth paragraphs). Applicants further allege that substituting the compounds of Muller et al. for the compounds of Gasper Elsas et al. and Waki et al. would not have been obvious (Remarks, page 8, second paragraph; page 9, third and last paragraphs). These arguments have been fully considered, but they are not persuasive.

The U.S. Federal Circuit has recently explicitly stated that in order to make a *prima facie* case of obviousness, the suggestion and motivation to combine the references need not be explicitly stated in the text of the references. In *DyStar*

Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 80 USPQ2d 1641 (Fed. Cir. 2006), the Court writes, "the suggestion test is not a rigid categorical rule. The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself. *In re Dembiczak*, 175 F.3d 994, 999 [50 USPQ2d 1614] (Fed. Cir. 1999). As we explained in *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1472 [43 USPQ2d 1481] (Fed. Cir. 1997), 'there is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art.'" See *Dystar* at 1645. "Our suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense." See *Dystar* at 1650.

In this case, the compounds of Gaspar Elsas et al., Waki et al., and Muller et al. were known in the art at the time of the invention to be PDE4 inhibitors, so the motivation to substitute one compound for another with the same function can be found in the common knowledge of the art and common sense of its skilled practitioners. As discussed at length in the final rejection, substituting equivalents known for the same purpose (*i.e.*, PDE4 inhibition) is obvious. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). See M.P.E.P. § 2144.06.

The art rejections of claims 1, 2, 6-9, 11, 13, 14, 16, 25, 26, 29, 30, 32, 33, and 102 stand. The enablement rejection of claim 11 stands. The indefiniteness rejection of claim 2 is overcome by this amendment after final rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SANDRA E. SAUCIER
PRIMARY EXAMINER

Lora E Barnhart

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